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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,348	07/29/2003	Navin Vaya	1296-016	9293

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,348	VAYA ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9-13,16-20,22-35,39-43 and 46-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-5, 9-13, 16-20, 22-35, 39-43, and 46-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2009 has been entered.

Summary

Claims 1-2, 4-5, 9-13, 16-20, 22-35, 39-43, and 46-61 are pending in this application.

Withdrawn Rejections/Objections

Claim Rejections - 35 USC § 112

The rejection of claims 1-2, 4-5, 9-13, 16-20, 22-35, 39-43, and 46-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants deletion of the term weight from the claim language.

The rejection of claims 1-2, 4-5, 9-13, 16-20, 22-35, 39-43, 46-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been

withdrawn in view of Applicants deletion of the term "ammonio methacrylate copolymers type A and B USP and methacrylic acid copolymer type A, B, and C, USP, polyacrylate dispersion 30% Ph.Eur" from the claims.

Maintained Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 4-5, 9-13, 16-20, 22-35, 39-43, 46-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (US Patent 6,600,300).

Timmins discloses a controlled release delivery system for pharmaceuticals which have high water solubility, such as antidiabetic metformin HCl salt. The delivery system includes (1) an inner solid particulate phase formed of substantially uniform granules containing a pharmaceutical having a high water solubility, and one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more hydrophobic materials such as one or more waxes, fatty alcohols and/or fatty acid esters, and (2) an outer solid continuous phase in which the above granules of inner solid particulate phase are embedded and dispersed throughout, the outer solid continuous phase including one or more hydrophobic polymers, one or more hydrophobic polymers and/or one or more hydrophobic materials such as one or more waxes, fatty alcohols and/or fatty acid esters, which may be compressed into tablets

(abstract). Timmins discloses high water solubility to be solubility in water at ambient temperature of at least about 50mg/mL water (column 9, lines 40-46).

The inner solid particulate phase may comprise 10-98% drug (column 9, lines 59-61). The extended release material in the form of hydrophobic polymers and/or other hydrophobic materials is in the range of about 5-95% by weight, based on the weight of the inner solid particulate phase (column 9, lines 62-67), which reads on the claimed weight ratio of drug: polymer particles of 100:2.5 to 100:30 as recited in the instant claims.

The inner solid particulate phase is in a weight ratio to the outer solid continuous phase is within the range of 0.5:1 to 4:1 (column 9, lines 54-58), which reads on the claimed weight ratio of particles: coating of 100:2.5 to 100:30 as recited in the instant claims.

Regarding claims 4-5, 11, 33-35, 41 hydrophobic polymers which may be employed in the inner solid particulate phase and/or outer solid continuous phase include, but are not limited to ethyl cellulose, hydroxyethylcellulose, ammonio methacrylate copolymer, methacrylic acid copolymers, methacrylic acid-acrylic acid ethyl ester copolymer, methacrylic acid esters neutral copolymer, dimethylaminoethylmethacrylate-methacrylic acid esters copolymer, vinyl methyl ether/maleic anhydride copolymers, their salts and esters (column 10, lines 44-55).

Regarding claims 10, 25, 40, 49-50, and 61 highly water soluble drugs, such as metformin, will be employed in a dosage range of 150-3000mg on a regimen in single daily doses or 2-4 divided daily doses, 1-4 times a day (column 20, lines 21-28).

Regarding claims 12-13 and 42-43, other hydrophobic materials which may be employed in the inner solid particulate phase and/or outer solid continuous phase include, but are not limited to waxes such as beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate, glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate, and hydrogenated castor oil (column 10, lines 56-65).

Regarding claim 19 and 48, Applicants attention is drawn to the table on the top of column 21 and Examples 1-4, which discloses 28-39% released at 1 hour, and between 75.7 through 93.1 at 6hrs (columns 21-23: Examples 1-4).

Since the prior art discloses the same composition as the instant claims, it is the position of the examiner that it would possess the same functional properties at the instant claims, with regard to plasma concentrations.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have optimized the ratio of particles to coating in order to alter the drug release profile. Timmins discloses, in a controlled release dosage form, the formulator tries to reduce the rate of dissolution by, for example, embedding the drug in a polymeric matrix or surrounding it with a polymeric barrier membrane through which drug must diffuse to be released for absorption. To reduce the rate of release of drug from the dosage form to an appropriate level consistent with the blood level profile desired for a drug possessing very high water solubility, very large amounts of polymer

would be required for the matrix or barrier membrane. If the total daily dose of drug to be delivered is of the order of only a few milligrams this may be feasible, but many drugs having the solubility properties described require total daily doses of the order of many hundreds of milligrams. Whilst it is possible to create oral controlled release dosage forms for such products by use of large amounts of polymer, an unacceptably large dosage form may result (column 2, lines 16-33).

Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). The optimization of the polymer coating would be a rate limiting/controlling variable.

Claims 24, 27-28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (US Patent 6,600,300) in view of Merck Index citations for niacin, sodium valproate, and nicotine.

The teachings of Timmins is disclosed above and applied in the same manner.

Timmins does not particularly disclose the use of niacin, sodium valproate, or one of the compounds disclosed in instant claim 24.

The Merck Index provides the following solubility's:

Niacin: One gram dissolves in 60 ml water.

Sodium valproate: One gram is sol in 0.4 ml water

Nicotine: Very sol in water.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted any highly soluble drug into the formulation of Timmins since Timmins discloses that any highly soluble drug is usable. One of ordinary skill would have the expectation of success since Timmins discloses numerous others highly water soluble drugs as well.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***the formulation of Timmins requires the use of hydrophilic polymers whereas the instant application only uses hydrophobic polymers.**

While it is acknowledged that Timmins uses hydrophilic polymers in his inner solid particulate phase, it is also noted that Applicant has used comprising terminology allowing for the inclusion of any additional components into the formulation regardless of their material effect on the composition.

***the final weight of the tablets of Timmins would be much larger than those of the instant claims.**

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., final size of the tablet/dosage size) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Timmins does not disclose a "dual retard technique".**

While it is acknowledged that Timmins does not use the claimed terminology, his final tablet formulation is with the scope of the instantly claimed tablet formulation. Applicant is as much acknowledges overlapping ranges of the polymer to active agents, and the use of identical matrix formulations. Therefore, it is the position of the Examiner that the instantly claimed tablets are obvious based on the teachings of Timmins. The fact that Timmins does not exemplify each and every possible embodiment within the claimed ratios does not negate the fact that he discloses them as suitable for use.

***Timmins does not teach a high solubility active ingredient.**

The Examiner respectfully disagrees. Timmins explicitly discloses a controlled release delivery system for pharmaceuticals which have high water solubility, such as antidiabetic metformin HCl salt. It is unclear what Applicant is basing the lack of a teaching on. Clarification is requested.

The rejections are therefore maintained for the reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615